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Dr. William Stokes  
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**Comment on the Background Review Document "EPISKIN, EpiDerm, and Rat Skin Transcutaneous Electrical Resistance (TER) – *In Vitro* Test Methods for Assessing the Dermal Corrosivity Potential of Chemicals"**

Dear Dr. Stokes

With regard to Federal Register Notice dated September 28, 2001 (Vol. 66, No. 189) I would like to comment on behalf of ZEBET at the BgVV on the NICEATM document mentioned above. Taking into account that ZEBET has been involved in the pre-validation and validation studies of the three methods for prediction of skin corrosivity potential, we will not comment on the methods themselves, but rather on the review (BRD), and the conclusions drawn.

1. The review is an excellent and comprehensive document compiling the information available on the validation status of the three methods.
2. Since the two skin model tests are similar with regard to exposure protocols of test materials, endpoints used, prediction models, and predictive power, we suggest a general "skin model corrosivity test" description would better cover the future use of other skin models, structurally and functionally performing in a comparable way. Of course, in this case, structure and performance criteria including a set of reference chemicals to be tested would have to be defined for evaluating any new skin model. This is the current approach at the OECD level, where attempts are made to define a general description for a skin model corrosivity test.
3. While the statement made in the BRD at several occasions (e.g. *Recommendations in the Executive Summary, page 9*) that the three tests are useful to reduce and refine the use of animals when used within testing strategies (e.g. specified in the OECD GHS, or updated OECD TG 404) is 100% correct for the testing of chemicals, there may be applications of the methods where the results can be used stand-alone. At the "OECD Extended Nominated Expert Consultation On *In Vitro* Skin Corrosivity Tests" (Berlin, November 1-2, 2001) it was agreed that there are applications where the assessment of only the corrosive potential of a chemical can be sufficient without being necessarily followed by an *in vivo* skin irritation/corrosion test in the rabbit, e.g. testing only for transportation regulations, or testing of chemical intermediates which are not placed on the market. **In these instances, the balanced small rate of false over- and under-predictions in the tests justifies a stand-alone use of the *in vitro* test results, including the classification "non-corrosive"**. In this context, it has to be taken into account that transport classifications of dangerous goods are often not based on biological test data.

We hope you can make use of the comments

Sincerely yours

Manfred Liebsch

PS: This statement reflects an agreed position of the BgVV chemicals department and BgVV-ZEBET but